PATENT
01236P00021US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In Re Application Of: | | ) Attachment Mechanism for ) Middle Ear Prosthesis |
| Patrick Antonelli et al. | | ) |
| | | ) Group Art Unit: 3738 |
| Serial No.: | 10/814,462 | ) |
| | | ) Examiner: Christopher D. Prone |
| Filed: | March 21, 2004 | ) |

**DECLARATION UNDER 37 CFR 1.132**

Anthony D. Prescott declares as follows:

1. I am a joint inventor named in the above-referenced application.

2. I received a Bachelor of Science Mechanical Engineering degree, with a concentration in Biomedical Engineering, from the University of Memphis in 1983. Since then, much of my career has been in fields related to the design and development of ossicular prosthetic devices (see Attachment A). I have been employed at Grace Medical, Inc, the assignee of the application, since about 1996.

3. I understand that Claim 30 of the application generally specifies a self-crimping ossicular prosthesis comprising a pair of jaws of a bioactive material. Each jaw comprises a body having a semi-cylindrical inner surface for engaging opposite sides of an ossicle when implanted in a human ear, to anchor to the ossicle. A spring element of a flexible material, different from the pair of jaws, is operatively coupled to the jaws for biasing the jaws toward one another to provide clamping pressure. An actuator element is operatively coupled to the spring element.

4. I understand that Claim 30 is rejected as anticipated by Muller et al. U.S. Patent No. 6,537,199 which discloses a device for mechanical coupling of a driver to a coupling site of the ossicular chain. The device includes a coupling element 35 in the form of a U-shape

spring clamp to partially surround a coupling site 16 of the ossicular chain. An attenuator 34 is disposed between the coupling element 35 and the coupling site 16 to protect against damage. The attenuator is indicated to be of an entropy-elastic or rubber-elastic material, preferably a silicone resin. I further understand that the Office action states silicone has a minor effect on a living organism and therefore concludes that silicone is bioactive.

5. Following is a brief description of some terms used within the biomaterials industry:

Biocompatible: The broadest term used to describe the lack of a toxic response to an implanted bio-material. A biocompatible material when placed in the body will not cause a strong systemic reaction leading to infection or evulsion of the material from the body.

Bioinert: A restriction of biocompatible materials to those which do not elicit a strong cellular response due to the presence of the material. Bio-inert materials do not release ions into the surrounding tissue. An example of this would be an Al2O3 ceramic acetabular cup. Bone will grow right up to the surface of the implant.

Bioactive: A very specific group of biocompatible materials which chemically interact with the surrounding tissue in such a manner as to promote a specific type of tissue response. Some examples of this are as follows: A hyroxylapatite implant releases calcium and phosphate ions into the surrounding bony tissue and stimulates the formation of an apatitic bond between the bony tissue and the implant. A stent coated with a controlled release substance prevents the formation of clots surrounding the stent.

Attachment B, an article entitlee "Middle Ear, Ossiculoplasty" also discusses these terms.

6. Given the above definitions following are further examples:

Stainless Steel: Biocompatible but neither bioinert nor bioactive. Stainless hip implants will become surrounded by fibrous tissue and will loosen from the femur unless bone cement is used to hold them in place.

Titanium: Bioinert: Titanium hip stems can be implanted directly into the femur without the need for bone cement. Bone will grow directly up to the surface of the implant.

Silicones: Biocompatible but neither bioinert nor bioactive. Silicones elicit a strong to moderate fibrous tissue reaction in the body. This can be a problem with such implants as breast implants. A Fibrous capsule will form around the implant which will cause hardening and loss of shape. This is why there are many attempts to modify the surfaces of silicone to make them "bioinert". An example is described in Attachment C.

7. The attenuator of Muller et al. is formed of an elastic silicone resin material. To perform its function the attenuator must retain its elastic properties. Column 5, lines 44-48 discusses non-rigidity or pliability of the attenuator. If the silicone chemically interacts with the surrounding tissue, i.e., the incus bone, then it would form a bond which would cause the attenuator to be which rigid and non-pliable, would render the device non-elastic in nature so that the attenuator would not function for its intended purpose.

All statements which I have made in this Declaration of my own knowledge are true, and all statements which I have made in this Declaration on information and belief are believed to be true. I have also been warned that willful false statements and the like are punishable by fine or imprisonment, or both under §1001 of Title 18 of the United States Code and may jeopardize the validity of this application or any patent issuing thereon.

Date: 3/6/2006

Anthony D. Prescott